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July 13, 2000

Office of Special Nutritionals (HFS-450) Center for Food Safety & Applied Nutrition Food and Drug Administration 200 C Street SW Washington, D.C. 20204

Dear Sir or Madam:

This letter will serve as 30-day notification, pursuant to section 403 (r)(6) of the Federal Food, Drug & Cosmetic Act and regulations promulgated thereunder.

Name and address of Dietary Supplement Manufacturer:

Twin Laboratories, Inc. 150 Motor Parkway Hauppauge, NY 11788

Text of statement being made: "Creatine plays an important role in the transfer of energy. In the muscle, it is used to fuel the process of contraction. It is converted to phosphocreatine which is important for short energy bursts needed for sprinting and weightlifting. Depletion of phosphocreatine can result in muscular fatigue and fading muscle power."

Dietary supplement ingredient: Creatine Monohydrate.

Dietary supplement brand and name: Twinlab MEGA CREATINE FUEL.

As required, enclosed are two photocopies of this notification.

The signee certifies that the information contained in this notice is complete and accurate, and that Twin Laboratories, Inc., has substantiation that the statement is truthful and not misleading.

Sincerely

Neil Blechman

Executive Vice President Twin Laboratories, Inc.

**Enclosures** 

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